

US EPA ARCHIVE DOCUMENT

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DATA EVALUATION REPORT

ZIRAM

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)

Prepared for

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

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Toxicology and Risk Analysis Section
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Task Order No. 97-22D

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

ZIRAM

Primary Dermal Irritation Study (OPP 81-5; OPPTS 870.2500)

EPA Reviewer: Virginia A. Dobozy, V.M.D., M.P.H., _____ Date _____

Reregistration Branch 1 (7509C)

Whang Phang, Ph.D., Branch Senior Scientist, _____ Date _____

Reregistration Branch 1 (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit
OPPTS 870.2500 [§81-5]

DP BARCODE: D235025

SUBMISSION CODE: S521512

P.C. CODE: 034805

TOX. CHEM. NO.: 931

TEST MATERIAL (PURITY): Ziram (Technical, 98.5%)

SYNONYMS: Zinc dimethyldithiocarbamate

CITATION: Liggett, M. and L. McRae (1990) Skin irritation to rabbits with Ziram (Technical). Huntingdon Research Centre Ltd., P.O. Box 2, Huntingdon, Cambridgeshire, PE18 6ES, England. HRC Study Report No. 90500D/UCB 317/SE, August 14, 1990. MRID 41643002. Unpublished.

SPONSOR: UCB Chemicals Corporation, 5505-A Robin Hood Road, Norfolk, VA 23513

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 41643002) six young male adult New Zealand White rabbits were dermally exposed to 500 mg Ziram (Technical, 98.5%, Batch no. 8331AA) moistened with 0.5 mL distilled water for 4 hours. Animals were then observed for 4 days. Irritation was scored by the method of Draize.

None of the animals showed any response to treatment throughout the observation period. **Based on the results, Ziram (Technical) is not an irritant to the skin of rabbits (Toxicity Category IV).**

This study is classified as acceptable (guideline). It does satisfy the guideline requirement for a primary dermal irritation study (81-5) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS1. Test material: Ziram (Technical)

Description: creamy white powder

Lot/Batch #: 8331AA

Purity: 98.5% a.i.

CAS #: 137-30-4

2. Vehicle

Distilled water

3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: ~10-13 weeks, 2.3-3.0 kg

Source: A. Smith, Warlingham, Surrey, England

Acclimation period: not given (acclimated to the laboratory environment)

Diet: SDS Standard Rabbit Diet, *ad libitum*

Water: tap water, *ad libitum*

Housing: individually in metal cage with a perforated floor

Environmental conditions:

Temperature: ~19°C

Humidity: 30-70%

Air changes: 19/hour

Photoperiod: 12 hour light/dark

B. STUDY DESIGN and METHODS1. In life dates

Start: March 6, 1990; end: March 9, 1990

2. Animal assignment and treatment

Six male animals were given a single 500 mg dose of Ziram (Technical) dermally applied under a 2.5 cm² gauze pad to a 10 cm² shaved site on the dorso-lumbar region. The test material was moistened with 0.5 mL distilled water and the application site covered with Elastoplast elastic adhesive dressing. The semi-occlusive dressing and the gauze pads were left in place for 4 hours, at which time they were removed and the application site washed with water. The site was scored for erythema and edema according to the Draize method on Days 1 (~30 minutes after removing the patch), 2, 3 and 4.

II. RESULTS AND DISCUSSION

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- A. None of the animals showed any response to treatment throughout the observation period. Based on the results, Ziram (Technical) is not an irritant to the skin of rabbits.

B. DEFICIENCIES

No study deficiencies were noted.

ZIRAM

Primary Dermal Irritation Study (OPP 81-5; OPPTS 870.2500)

SignOff Date:	8/2/00
DP Barcode:	D172447
HED DOC Number:	014277
Toxicology Branch:	RAB2